IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Hi-Tech Pharmaceuticals Inc.,

Plaintiff,

v. Case No. 1:16-cv-949-MLB

Dynamic Sports Nutrition, LLC, et al.,

Defendants.

_____/

OPINION & ORDER

At pretrial hearings, the Court notified the parties of its decision to deny Plaintiff's motion to exclude expert testimony from Anthony Fontana (Dkt. 236), grant in small part Plaintiff's motion to exclude testimony from Craig Lindsley (Dkt. 238), and grant Defendants' motion to exclude testimony from Linda Gilbert (Dkt. 213). This order supplements the Court's prior conclusions.

I. Background

Plaintiff Hi-Tech Pharmaceuticals Inc. manufactures and sells dietary supplement products, including DIANABOL® and a number of

products designed for muscle and body building, hormone boosters, and weight loss aids. (Dkt. 163-2 at 2–3.) On February 5, 2008, the United States Patent and Trademark Office ("PTO") issued a registration for DIANABOL® as a trademark (Registration No. 3,378,354) for use in the pharmaceutical class of trademarks (Class 5) in connection with certain "dietary supplements, excluding anabolic steroids." (Dkt. 64-1.)

For more than a decade Defendant Dynamic Sports Nutrition, LLC, ("DSN") has sold and marketed dietary supplement products, including D-Anabol 25. (Dkt. 160-1 ¶ 22.) In March 2011, DSN applied to the PTO to register D-Anabol 25 as a trademark for dietary supplements. (Dkt. 62 ¶ 21.) On June 28, 2011, the PTO issued an office action refusing the registration because (1) there was a likelihood of confusion with the DIANABOL® trademark; (2) D-Anabol 25 was merely descriptive of a feature of the product; and in the alternative, (3) the product was deceptively misdescriptive. (Dkt. 62-2 at 2–5.)

On February 5, 2014, Plaintiff filed an affidavit with the PTO certifying that (1) the goods associated with DIANABOL® have been in continuous use for five consecutive years and are still in use in commerce; (2) no final decision exists that is adverse to the owner's claim of

ownership of DIANABOL® for such goods, or to the owner's right to register the same or to keep the same on the register; and (3) there is no proceeding involving the trademark rights pending in the PTO or in a court. (Dkt. 54-17.) The PTO found Plaintiff's affidavit met the requirements of the Trademark Act, 15 U.S.C. §§ 1058 and 1065, and the DIANABOL® mark was thus incontestable. (Dkt. 54-18.)

Plaintiff then sued Defendant DSN and its owner, Brian Clapp. (Dkt. 62.) The Complaint includes claims for trademark infringement (Counts I & II); false designation of origin and unfair competition (Counts III & IV); false advertising (Count V); violation of the Georgia Deceptive Trade Practices Act (Count VI); common law unfair competition (Count VII); and violations of the Georgia Racketeer Influenced and Corrupt Organizations Act ("RICO") (Counts VIII through X). Defendants assert several defenses, including that DIANABOL® is generic, that the DIANABOL® trademark was obtained by fraud, and that Plaintiff has unclean hands. (Dkt. 67.) As the parties prepared for trial, they filed a series of motions to preclude various experts from testifying. (Dkts. 213; 236; 238.)

II. Legal Standard

Trial courts serve a critical gate-keeping function for the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Expert testimony can be particularly persuasive, and as such, the role of the trial court is to keep speculative and unreliable testimony from reaching the jury. *Id.* at 595; *see McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002).

Federal Rule of Evidence 702 allows a qualified expert to give opinion testimony when it is necessary to help the trier of fact understand the issues, the opinion is based on sufficient facts or data, the expert produced it using reliable principles and methods, and those principles and methods were reliably applied to the facts of the case. Fed. R. Evid. 702. The Eleventh Circuit employs a "rigorous" three-part inquiry to determine whether an expert's testimony meets these admissibility criteria. *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). Expert testimony is admissible when

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and

> (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Id. (footnote omitted). Thus, the admissibility of an expert's opinion turns on three things: qualifications, reliability, and helpfulness. *See United States v. Frazier*, 387 F.3d 1244, 1260–62 (11th Cir. 2004).

While the trial court's role is critical, it "is not intended to supplant the adversary system or the role of the jury." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1311 (11th Cir. 1999). When the accuracy of evidence is the issue—as opposed to its admissibility—the trial court should allow the judicial process to resolve the matter. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

III. Discussion

A. Plaintiff's Motion to Exclude Expert Testimony From Dr. Anthony Fontana

Plaintiff retained Banned Substances Control Group ("BSCG") to test DIANABOL®. BSCG is a wholly owned subsidiary of Anti-Doping Sciences Institute. (Dkt. 236-6 at 1.) Anti-Doping Sciences Institute contracted with Truesdail Laboratories Inc. ("Truesdail"), which tests

nutritional supplement products for banned substances, to conduct the testing. (*Id.*) Dr. Fontana is the Technical Director and Chief Science Officer of Truesdail. (*Id.*) Dr. Fontana issued an expert report opining, among other things, that DIANABOL® contains anabolic steroids, androstenedione, dihydrotestosterone ("DHT"), and dehydroepiandrosterone ("DHEA"). (Dkt. 236-6.) Defendants claim this evidence shows Plaintiff knowingly and intentionally "spiked" DIANABOL® with steroids and that this evidence is relevant to show Plaintiff's DIANABOL® mark was obtained through fraudulent filings and that Plaintiff has unclean hands. (Dkts. 160 at 15-19; 215 at 7, 9, 17.) More specifically, they say the evidence will show that "Hi-Tech and Wheat have engaged in an on-going, twenty-year scheme of USPTO-related fraud by obtaining marks similar or identical in name to common, illegal muscle-building steroids and then spiking those supposedly legal products with banned anabolic steroids[, that] include[] DIANABOL®." (Dkt. 215 at 8.)

Plaintiff moves to exclude his testimony. (Dkt. 236.)

1. Dr. Fontana's Background

Dr. Fontana has served as the Technical Director and Chief Science Officer of Truesdail since 2014. (Dkts. 236-6 at 10; 236-4 at 18:8–12.) In that role, he "[o]versees all day-to-day laboratory activities; research and procurement of instrumentation, oversight of senior management, specialized areas of testing, proposal and bid preparation, and develops standard operating procedures"; "[p]rovides senior program and project management, manpower planning, obtains outside certifications, and interacts with regulator agencies"; and "[r]eviews technical data packages and reports." (Dkt. 236-6 at 10.)

Dr. Fontana received his Bachelor of Science in Biochemistry from the University of California, Riverside and his Ph.D in Agricultural and Environmental Chemistry from the University of California, Davis. (*Id.*) After completing his Ph.D, Dr. Fontana was a senior scientist at Thermalytics, Inc., where he was a Principal Investigator for the Department of Energy, Phase I, Small Business Innovation Research Project. (*Id.*) He later became a Senior Research Scientist at Decagon Devices, Inc., in a food and pharmaceutical analysis lab, where he conducted research and collaborated with researchers in new technology

development. (Dkts. 236-6 at 10; 236-4 at 14:16–15:3.) Before joining Truesdail, Dr. Fontana was the Technical Director of Chemistry at Silliker, Inc., a food testing, food analysis, and food safety lab specialized in nutritional labeling, allergen testing, and prohibited drug testing. (Dkts. 236-6 at 10; 236-4 at 14:5–14, 15:14–19.) In that position, he provided scientific, application, and technical support to clients, interpreted laboratory data, and provided consulting. (Dkt. 236-4 at 15:14–19.) Dr. Fontana has over 40 published papers and presentations on environmental and nutritional analysis and analytical methods development. (Dkt. 236-6 at 10.)

2. Truesdail's Testing Procedures

Truesdail is an International Standardization Organization accredited testing laboratory (ISO/IEC–170251 and 170652) and Racing Medication & Testing Consortium accredited testing laboratory. (Dkt. 236-6 at 1–2.) Included in Truesdail's ISO/IEC 17025 Scope of Accreditation is instrumental screening and confirmation of chemical identity of Nutritional Supplements. (*Id.* at 2.) Truesdail uses international, agreed-upon guidelines for identifying compounds by chromatography and mass spectrometry. (*Id.*) In his role as Technical

Director, Dr. Fontana develops the standard operating procedures ("SOPs") for testing, which all laboratory technicians must follow. (*Id.* at 10.) The SOPs contain a list of set protocols, such as the requisite temperature and gas flow for the testing instruments. (Dkt. 236-4 at 48:01–49:13.) The SOPs do not require (or permit) the lab technicians to exercise any judgment or discretion. (*Id.*)

Dr. Fontana's report and deposition testimony explains Truesdail's testing process from start to finish in great detail. When Truesdail receives a sample or batch, a laboratory technician inspects the sample and observes any evidence of damage or tampering with the container. (*Id.*) The sample is then logged into the Laboratory Information Management Systems and assigned a Sample ID Number. (*Id.*) Later, a portion of the sample, called an aliquot, is taken from the original container for screening tests. (Dkt. 236-6 at 2.) Any time a subsequent aliquot is taken, the sample goes through the same procedure. (*Id.*)

Aliquots are extracted by a method of liquid-liquid extraction, which isolates the acid/neutral fraction containing possible anabolic steroids. (*Id.* at 3.) Before the sample is tested, the conditions on the instruments are set up in accordance with the SOPs. (Dkt. 236-4 at 49:2–

6.) The extracted aliquots are then screened using a liquid chromatography/mass spectroscopy ("LC/MS") test which utilizes Ultra-High Performance Liquid Chromatography and High-Resolution Mass Spectroscopy. (Dkt. 236-6 at 3.) Ultra-High Performance Liquid Chromatography uses pumping systems that deliver high pressures to chromatography columns. (*Id.*) Samples are then forced by liquid at high pressure (mobile phase) through the column, which is packed with particles that are designed to accomplish separation (stationary phase). (*Id.*) The retention time of the sample compounds in the stationary phase provides an identifier as to the nature of the compound. (*Id.*) High-Resolution Mass Spectroscopy measures the mass-to-charge ratio of charged particles to determine the elemental composition of compounds from their mass fragments. (*Id.*)

After this initial testing is completed, the stored data is evaluated using software algorithms and a chemist's review. (*Id.*) If the initial sample identifies the presence of suspected material, a new aliquot of the sample is extracted for confirmatory testing. (Dkt. 236-4 at 29:21–30:6, 601:13–61:14.) The reshoot is performed on an Ultra-High Performance Liquid Chromatography Mass Spectroscopy triple quad, which allows for

a more targeted and sensitive screen, since the "suspected" drugs have already been identified. (*Id.* at 30:07–31:02.) The reshoot/confirming test is a multi-step process that analyzes at least two extracts from the sample under examination, a control sample containing the suspected drug or metabolite, a negative control samples, and five control samples spiked with the suspected drug or metabolite. (Dkt. 236-6 at 6.) The LC/MS test measures both the liquid chromatography (retention time) and mass spectrometer (peak ratio) for all samples. (*Id.*) A comparison of the retention times and mass peak ratios between the samples under examination and the control samples allows Truesdail to determine the presence of the suspected drug in the sample. (*Id.*) "The goal of the confirmatory testing is to provide incontrovertible identification of the detected substance by concentrating and purifying the suspect drugs or drugs." (*Id.* at 5.) Quantification of drugs is done through another analysis. (*Id.*)

If the data from the reshoot confirms the presence of the suspected compound, a positive report is completed. (*Id.*) If the confirmatory test still identifies the sample as only "suspect" for the drug or metabolite, the laboratory extracts a new portion of the sample and applies other

procedures. (*Id.* at 7.) If the confirmatory test determines the suspected drugs or metabolites are not present, the sample is cleared. (*Id.*) A data packet containing the testing results, chain of custody information, and laboratory testing results is maintained by the company. (*Id.* at 6.)

3. Dr. Fontana's Report

On May 6, 2016, Truesdail received a sample of Hi-Tech's DIANABOL® (Lot #: 152200608) that was logged and processed under Sample ID Number: 16505090-01. (*Id.* at 2.) Truesdail was tasked with conducting a batch certification test for steroids on the DIANABOL® sample. (*Id.*) Three days later, Minh Do, a laboratory technician at Truesdail, extracted a sample of DIANABOL® for testing, which was subsequently screened for anabolic steroids via LC/MS by Truesdail employee Dale Park. (Dkt. 236 at 2.) The LC/MS screening detected the presence of androstenedione, dehydroepiandrosterone ("DHEA"), and DHT. (Dkt. 236-6 at 6.)

In accordance with the SOPs, Truesdail performed confirmatory LC/MS tests for androstenedione, DHEA, and DHT on August 12, 2016. (*Id.*) The second screens confirmed the presence of all three steroids. (*Id.* at 7–8.) Truesdail subsequently generated a data packet which contains

all the data from the testing, as well as information regarding chain of custody, receipt of the sample, and preparation of the aliquots for testing. (Dkt. 236-4 at 8:22–9:05.) Dr. Fontana's report is based on his analysis of the data packet. (*Id.*)

Dr. Fontana concluded that the LC/MS tests confirmed the presence of androstenedione, DHEA, and DHT in DIANABOL® with respect to both the liquid chromatograph (measuring retention time) and mass spectrometer (measuring peak ratio) aspects of the tests. (Dkt. 236-6 at 7.) With regard to the quantitative confirmatory test for androstenedione, Dr. Fontana explained that the retention time of the injection standard of androstenedione was 219.6 seconds, and the retention times of the sample from Plaintiff's DIANABOL® (identified as sample 1605090), the spiked sample, and the second androstenedione standard was 220.2 seconds, 219.6 seconds, and 220.2 seconds, respectively. (*Id.*) To confirm the presence of androstenedione, the target differential in retention times between all these injections must be less than 2% (or within 12 seconds). (*Id.*) Dr. Fontana explained that Truesdail's analysis of DIANABOL® met this standard. The retention differential between all the injections at issue here was within 0.6

seconds, thus confirming the presence of androstenedione in DIANABOL®. (*Id.*)

He also explained that the peak ion ratio check for three ions confirmed the presence of androstenedione. (*Id.*) He explained that the mass spectrometer analysis requires acceptable ion ratio based on relative abundance to confirm the detection of the targeted substance. (*Id.*) Here, the differential ranged from 0% to 7.54%, confirming the presence of androstenedione in the sample.

Dr. Fontana engaged in a similar analysis for the confirmatory tests for DHEA and DHT. The retention time of the injection standard of DHEA was 220.2 seconds. (*Id.* at 7–8.) The retention times of the sample from Plaintiff's DIANABOL® (identified as sample 1605090), the spiked sample, and the second DHEA standard was 220.2 seconds, 220.2 seconds, and 220.8 seconds, respectively. (*Id.* at 8.) The target differential in retention times to confirm the presence of DHEA is less than 2% between all these injections or within 12 seconds. (*Id.*) Here, it was within 0.6 seconds, thus allowing Dr. Fontana to confirm the presence of DHEA. (*Id.*) And the mass spectrometer analysis differential

ranged from 0% to 3.49%, also confirming the presence of DHEA in the sample.

Finally, the retention time of the injection standard of DHT was 229.2 seconds. (*Id.* at 7–8.) The retention times of sample 1605090-01, the spiked sample, and the second DHT standard was 227.4 seconds, 229.8 seconds, and 229.8 seconds, respectively. (*Id.* at 8.) Again, the target differential in retention times to confirm the presence of DHT is less than 2% between all injections or within 12 seconds. (*Id.*) Here, it was within 2.4 seconds, and Dr. Fontana thus confirmed the presence of DHT. (*Id.*) Finally, the mass spectrometer analysis differential ranged from 0% to 15.93%, also confirming the presence of DHT in the sample.

4. Plaintiff's Daubert Motion

Plaintiff moved to preclude Dr. Fontana from testifying, arguing under *Daubert* and Federal Rule of Evidence 702 that Dr. Fontana is not qualified to testify as an expert because he did not perform the DIANABOL® testing himself and that his conclusions are not based on any reliable methodology.

a) Dr. Fontana is Qualified to Render the Opinions in his Expert Report.

Dr. Fontana is sufficiently qualified. Federal Rule of Evidence 702 provides that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. To determine an expert's qualification, a trial court must "examine the credentials of the proposed expert in light of the subject matter of the proposed testimony." *Jack v. Glaxo Wellcome, Inc.*, 239 F. Supp. 2d 1308, 1314 (N.D. Ga. 2002). Dr. Fontana obtained his Bachelor of Science degree in biochemistry and a Ph.D in chemistry. (Dkt. 236-6 at 11.) He has been a laboratory chemist for over 25 years and has served as Truesdail's Chief Science Officer and Technical Director since 2014. (*Id.* at 1.) Dr. Fontana's specialty at Truesdail is largely related to testing equine blood urine for steroids. (Dkt. 236-4 at 19:18–21.) This means he has experience in the analysis directly at issue—that is, detecting the presence of steroids (or lack of steroids) in a known sample. And before Truesdail, Dr. Fontana's experience was at a food and pharmaceutical analysis lab and before that at a food testing and food safety analysis lab that specialized in nutritional labeling. (Dkt. 236-6 at 1.) He has a

lifetime of experience in laboratory testing to detect the presence (or lack thereof) of suspect compounds.

Plaintiff contends the relevant issue before this Court is the performance of the LC/MS testing (not upper management of a lab's day to day activities) and Dr. Fontana lacks the specialized knowledge required to testify about the former. (Dkt. 236 at 14.) Plaintiff argues that Dr. Fontana is not qualified to testify regarding the results of the DIANABOL® testing because there is no evidence he has ever operated the LC/MS machine, received LC/MS instrumentation training, or performed the tests or operated the instruments himself. (*Id.*) But Plaintiff's view is too narrow—Dr. Fontana oversees all activities in the lab, including testing, and Dr. Fontana has the relevant expertise permitting him to analyze and explain the data. As a part of his responsibilities at Truesdail, Dr. Fontana sets the SOPs for testing and performs a technical review of the data from the drug testing laboratory—including LC/MS testing. (Dkt. 236-4 at 18:13–18.)

The detailed analysis he included in his report and offered during his deposition demonstrate Dr. Fontana's qualifications as an expert in LC/MS testing. In his deposition, for example, Dr. Fontana spoke about

the two machines Truesdail used to conduct the first initial screening and the second confirmatory test. He explained that the first test was conducted on a "UHPLC time-of-flight mass spec[trometer]" while the confirmatory test was done with the "UHPLC mass spec[trometer] triple screen." (Dkt. 236-4 at 30:7–16.) When asked about the difference, he explained "[t]he initial screening is a high-resolution mass spectrometry . . . [that] looks for molecular weights and identifies the compounds on very small mass differences," while the second is "more of a targeted screen . . . [that] identif[ies] the particular compounds . . . [b]ased on retention time and ion mass fragments." (*Id.* at 30:17–31:5.) He explained the first test merely identifies suspected compounds in the sample and the second confirms (or excludes) the presence of those compounds. (*Id.*) He explained the three steps of the triple quad machine—"the first quadrupole where the ions are separated into the compounds that you're looking for," the "second stage . . . which is the collision stage [where] nitrogen gas is infused and basically fragments

the molecules into different ions," and then the "third quadrupole into the detector." (*Id.* at 88:6–21.)

He also testified that, under his supervision, the laboratory adopted SOPs that technicians follow to screen for drugs, that the SOPs also establish the instrument setting for each test, and that technicians have no discretion to alter the settings. (*Id.* at 32:20–22, 49:2–14.) He walked through the protocol technicians followed to analyze compounds, including when solvents are added to the samples, the use of high frequency radio waves to "sonicate" the samples to distribute the solvents, the use of a centrifuge to "precipitate or pellet all the remaining solid material," the "liquid extraction" of organic matter floating on the "aqueous layer" to be tested, the use of nitrogen and methanol to evaporate the solvents and redissolve the remaining compounds, and other steps taken to test each sample, calibrate the machines, and confirm test results are reliable. (*Id.* at 52:7–56:20, 74:8–92:7.) Finally, he walked through the charts in the data packet, explained what the numbers and figures represented—that is how the results of the testing according to the SOPs revelated the presence of steroids in DIANABOL®. (*See e.g.*, Dkt. 236-4 at 86:24–87:11 ("[O]n the left side of the page, is the

three ion fragments that were identified for androstenedione in this case . . . [and o]n the right-hand side, that's the internal standard, that deuterated testosterone that was added to the sample . . . [a]nd that's the ion for that standard.").)

His testimony showed clear expertise in the SOPs he implemented for use by technicians on the LC/MS machines, their use in analyzing samples, and the analysis of their results to identify the presence or absence of steroids. All of this, along with his extensive experience in laboratories specializing in testing of food and pharmaceuticals, especially testing that involves the identification of steroids, render Dr. Fontana well qualified to testify as an expert that DHEA, DHT, and androstenedione were present in the sample of DIANABOL®.

b) Reliability of Dr. Fontana's Report

The Court also finds Dr. Fontana's report and testimony to be sufficiently reliable. Plaintiff's principle argument is that Dr. Fontana is merely "parroting" the opinions of Mr. Park (the lab technician who ran

the LC/MS testing) and did not apply any of his own methodology in creating the report. (Dkt. 236-6 at 15.)

An expert witness is permitted to use assistants in formulating his or her expert opinion, and normally they need not themselves testify. *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612 (7th Cir. 2002). But the analysis becomes more complicated if the assistants are not "merely gophers or data gatherers but exercise professional judgment that is beyond the expert's ken." *Id.* at 613. "It is well settled that an expert may rely on the work of assistants when formulating an expert opinion, but may not simply parrot the work actually done by another expert, who is not offered for testimony and cross-examination." *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 729 (E.D.N.C. 2007). Although Rule 703 permits experts to rely on the opinions of other experts in some circumstances, "the expert witness must in the end be giving his *own* opinion. He cannot simply be a conduit for the opinion of an unproduced expert." *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007) (emphasis in original). Absent an independent opinion based upon a reliable methodology, the expert is "little more than a conduit or transmitter for [] hearsay." *United States*

v. McLean, 695 F. App'x 681, 685 (4th Cir. 2017). Under the Federal Rules of Evidence, the "facts and data" upon which an expert bases his opinions do not have to be personally known to him, but may instead be "made known" to him by "presentation . . . outside of court and other than by his own perception." *See* Fed. R. Evid. 703 & Advisory Committee Notes. In making the determination of whether an expert's reliance on another expert's assistance is permitted, courts also consider whether the information is "of the type on which experts in this field would reasonably rely." *See Erebia v. Allstate Prop. & Cas. Ins. Co.*, No. 1:15-CV-312-MHC, 2016 WL 4435089, at *6 (N.D. Ga. July 18, 2016) (holding that plaintiff's expert was permitted to rely upon the assistance of his employee when developing opinion; although employee acquired data, took measurements, and input that data into the computer, "the evidence before the Court d[id] not support the position that [the expert's] report was other than his own opinion").

The Court finds Dr. Fontana's reliance on the test results to be proper in this case. As an initial matter, Dr. Fontana is not "parroting" any *opinions* in the data packet. Dr. Fontana sets the SOPs for the testing, and Mr. Park was required to follow those without exercising any

independent professional judgment. (Dkt. 236-4 at 48:01–49:13.) The only component of Dr. Fontana's report that is taken directly from the data packet is the raw data. Dr. Fontana explains in detail how samples are received, how aliquots are tested, how the testing process works, why particular machines are used, how he analyzed the raw data, and why it led to his conclusions in the report. (*See* Dkt. 236-6 at 1.) For example, in regard to the androstenedione screening, Dr. Fontana testified that he performed the final review of the data packet and explained that "[i]t shows retention times of the opening standard in solvent, the sample, the one of the standards – control positive standards, and then the closing standard for retention time shift and monitoring on that. Has the mass ion ratios on there and then the acceptance criteria for three ions." (Dkt. 236-4 at 95:25–96:16.) Then, in his expert report, Dr. Fontana explains that the retention time of the injection standard of androstenedione was 219.6 seconds, and the retention time of sample 1605090, the spiked sample, and the second androstenedione was 220.2 seconds, 219.6 seconds, and 220.2 seconds, respectively. (Dkt. 236-6 at 7.) The target differential in retention times to confirm the presence of androstenedione is less than 2% between all these injections or within 12 seconds. (*Id.*)

And because the retention differential between all the injections was within 0.6 seconds, Dr. Fontana confirmed the presence of androstenedione. (*Id.*) His report shows that he did the same analysis to conclude DIANABOL® also contains DHEA and DHT. Dr. Fontana's testimony and expert report make clear that, while he relied on Mr. Park to run the tests in accordance with Truesdail's SOPs, Dr. Fontana then analyzed the data himself, thus offering an opinion that the data shows the presence of the identified steroids.

Numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts for purposes of Federal Rule of Evidence 703. *See e.g., Ratliff v. Schiber Truck Co.*, 150 F.3d 949, 955 (8th Cir. 1998) (holding that expert testimony regarding a report prepared by a third party was properly allowed); *see also Gussack Realty Co. v. Xerox Corp.*, 224 F.3d 85, 94, 95 (2d Cir. 2000) (finding testimony was properly admitted from an expert who did not conduct his own tests).

Nor does the Court find Dr. Fontana's report to be inadmissible hearsay of Mr. Park's conclusions in the data packet. Plaintiff' cites *Tokio Marine & Fire Insurance Co. v. Norfolk & Western Railway Co.*, 172 F.3d

44 (4th Cir. 1999) (per curiam), to argue otherwise. But there, the witness who sought to give expert testimony conceded that the opinions in the report belonged exclusively to someone else, and the witness merely agreed with that person's opinion. The court found that, because the opinion belonged to someone else, cross-examination of that witness could reveal nothing about the mental processes by which the opinions in the report were reached. *Id.* Here, however, Dr. Fontana's testimony provides details and insight into the testing procedures and the mental processes by which he concluded that androstenedione, DHEA, and DHT were present in the DIANABOL® sample. Dr. Fontana's report contains his own independent opinions based on his years of expertise and involvement developing and overseeing the testing procedures at Truesdail. As a result, the Court finds the report and testimony of Dr. Fontana to be reliable and helpful to the trier of fact. Plaintiff can cross examine Dr. Fontana about the fact that he did not personally test the DIANABOL® sample, which will go to the weight and credibility of his testimony, but the Court will not exclude his report or prohibit him from testifying. Because the Court finds Dr. Fontana is qualified and his

methodology was reliable, Plaintiff's motion to exclude Dr. Fontana's report and testimony is denied.

B. Plaintiff's Motion to Exclude Expert Testimony of Testimony of Dr. Craig Lindsley

Plaintiff plans to call Dr. Marvin Heuer as an expert witness to opine on various aspects of Defendants' products, including apparently that its products do not do for consumers what DSN says they will do. (Dkt. 241 at 1; *see also, e.g.,* Dkt. 163-18 ¶ 51 (consumption of ingredients in DSN's D-Anabol 25 "could not result [in] increased muscle mass, size, or strength"), ¶ 64 (consumption of ingredients in DSN's Winn-50 "are not shown . . . to have any fat reduction capability"), ¶ 77 (ingredients in DSN's Var-10 "could not have any impact on athletic performance").) In his report, Dr. Heuer concluded:

> Consumption of the ingredients as purportedly present in [Defendants'] products would have none of the physical effects advertised by Defendants. Some of the ingredients would not have any noticeable effect on the human body, even in large does, and the ingredients that could have noticeable effects are not present in sufficient amounts to do so.

(Dkt. 163-18 at 71.) As the basis for his opinion, Dr. Heuer cites "the absence of scientific literature and evidence to support Defendants' product claims, the existence of scientific literature establishing the

actual effects of the various ingredients (which do not include those advertised), [his] experience and training as a physician and chemist, and generally accepted principles in the scientific community." (*Id.*)

Defendants retained Dr. Craig Lindsley as a rebuttal expert. (Dkt. 238-2 at 1.) Plaintiff seeks to exclude all evidence and testimony of Dr. Lindsley, claiming Dr. Lindsley is not qualified to provide expert testimony on the subject matter contained in Dr. Heuer's report, that he has no reasonable basis for his opinions because he applied no methodology, and that his testimony would not be helpful to the jury. (Dkt. 238 at 1.)

Dr. Lindsley received his B.S. in chemistry from California State University, Chico in 1992, received his Ph.D in chemistry from the University of California, Santa Barbara in 1996, and served as a Postdoctoral Fellow at Harvard University from 1997–1999 at the Harvard Institute of Chemistry and Cell Biology. (Dkt. 238-2 at 12.) Dr. Lindsley's focus throughout his education was synthetic organic chemistry, with an emphasis on synthetic methodology, total synthesis, and chemical biology. (Dkt. 238-1 at 7:22–7.) Dr. Lindsley's

specialization deals with the effect of certain chemicals on the body. (*Id.* at 8:3–7.)

Dr. Lindsley is currently the William K. Warrant, Jr. Chair in Medicine, Professor of Pharmacology,[1] and Professor of Chemistry at Vanderbilt University. (Dkt. 238-2 at 12–13.) He also serves as the Co-Director and Director of Medicinal Chemistry and DMPK at Vanderbilt Center for Neuroscience Drug Discovery, Associate Director of Therapeutics at Vanderbilt Institute of Chemical Biology, Director of Drug Discovery at the Human Chemical Science Institute, Principal Investigator at Vanderbilt MLPCN Specialized Chemistry Center, and Editor-in-Chief of American Chemistry Society Chemical Neuroscience. (*Id.*) Dr. Lindsley is the former Co-Director of the VICB Synthesis Facility and former Director of the Vanderbilt MLSCN Chemistry Molecular Probe Center. (*Id.*)

Before entering academia, Dr. Lindsley was a senior scientist in Medicinal Chemistry at Parke-Davis Pharmaceuticals, a senior organic chemist at Eli Lilly & Co., and a senior research chemist, research fellow,

[1] Pharmacology is the study of molecules on biological targets. (Dkt. 238-1 at 23:3–5.)

and senior research fellow at Merck Research Laboratories. (*Id.* at 13.) He holds 74 patents and has authored nearly 500 articles, reviews, and other published papers. (*Id.* at 20–85.) Dr. Lindsley has not done any work with dietary supplements and does not have any education or training with regard to dietary supplements. (Dkt. 238-1 at 6:15–20, 7:17–21.)

1. Dr. Lindsley's Report and Expert Opinions

Dr. Lindsley offers a panoply of expert opinions regarding Dr. Heuer, Dr. Heuer's opinions in this case, and DSN's practices.

a) Polypharmacy

Dr. Lindsley opines that Dr. Heuer erroneously looked at Defendants' product ingredients in isolation—that is, how any single ingredient might affect the human body—rather than DSN's proprietary blend—that is, how all the ingredients together might affect the human body. He explained that "these are novel 'proprietary blends' of multiple components, it is a novel composition with novel pharmacological and pharmacodynamic properties that must be tested and assessed as the 'proprietary blend' in order to determine actual exposure in a human, and thus pharmacology." (Dkt. 238-2 at 7–8.) In his deposition testimony, Dr. Lindsley further explained that "any conclusions drawn from a

discrete isolated molecule does not necessarily translate to a blended product with multiple ingredients in terms of, again, its exposure." (Dkt. 238-1 at 64:9–15.) Dr. Lindsley also explained the ramifications of looking at compounds from a pharmacological standpoint:

> [A]ny time you take a -- something that's a mixture of different components, you're going to get different pharmacology, because again, the way -- the degree -- how these compounds can affect absorption, how they can affect metabolism of the other species. You know, if one of these inhibited P-gp on the intestinal wall, you get more exposure or less.

(*Id.* at 90:10–16.)

b) Dosage

Dr. Lindsley also criticized Dr. Heuer for having considered only how a single dose of Defendants' product might affect the human body, rather than how the accumulation of ingredients over multiple doses might impact the body. He notes that Defendants' website makes explicitly clear that the recommended dosage for all but two of Defendants' products, including D-Anabol, is 3 capsules per day. (Dkt. 238-2 at 8–9.) In his report, Dr. Lindsley testifies that the "single capsule basis" of Heuer's assessment regarding Defendants' product ingredients, rather than an assessment based upon the recommended multiple capsules dosages, "will dramatically effect exposure and steady state

pharmacokinetics." (*Id.*) He opines that Dr. Heuer's per-capsule characterization of the quantity of certain ingredients as "miniscule" is not accurate because Defendants' recommended dose include three times the ingredients Dr. Heuer considered and because Defendants' proprietary blend could result in "significantly higher" exposure for humans upon consistent dosing. (*Id.* at 9.)

c) Lack of Studies

Dr. Lindsley notes that "there is very little scientific data [in peer-reviewed, scientific papers in scientific journals] on the efficacy of dietary supplements" and that such a study "would have to be performed on the actual 'proprietary blend' and at the appropriate dose to reach a reliable conclusion about the product claims." (*Id.* at 5, 9.) Dr. Lindsley explains that Dr. Heuer is drawing conclusions from single agent exposure and ingredient-specific studies and applying them to Defendants' products which are proprietary blends. He says, again, this is inappropriate because it is impossible to know what impact a blend is going to have on human pharmacokinetics. (Dkt. 238-1 at 93:19–94:1, 102:6–14.)

d) Patents

Based on Dr. Heuer's statement that he has "filed several patents and provisional patents on new and emerging compounds not unlike the ingredients and products marketed by the defendants," Dr. Lindsley opines that there is a conflict of interest with Dr. Heuer testifying as an expert because Dr. Heuer or a Heuer-related entity may well have patent-related interests that will benefit in DSN's removal from the marketplace. (Dkt. 238-2 at 3.) Dr. Lindsley's experience is that, when he serves as an expert, he is "walk[ed] through a litany of, '[d]o you have any conflict with this drug, this mechanism, this target class, this company, that company,' and if you have any kind of overlapping interest of any kind, you're excluded from serving in that case because of the conflict." (Dkt. 238-1 at 39:10–20.) He says Dr. Heuer should have done the same and recused himself from this case.

e) COPE Violations

In his report, Dr. Heuer states that he has written or reviewed articles on behalf of various entities and has also been an "unnamed writer" on several papers. (Dkt. 163-18 ¶ 29.) Dr. Lindsley criticizes him for this, saying being an unnamed author violates standards put out by the Committee on Publication Ethics ("COPE"). (Dkt. 238-2 at 3–4.)

f) Ioavate Health Services International

Dr. Heuer was Chief Science Officer for Iovate Health Science International from 2004 to late 2009. (*Id.* at 3.) Dr. Lindsley's report includes a screenshot of a Federal Trade Commission ("FTC") press release describing consumer refunds issued as a result of challenged marketing practices by Iovate, noting that these marketing practices "occurred while Dr. Heuer was Chief Science Officer for Iovate Health Sciences International in Canada." (*Id.* at 4.)

g) DSHEA Violations

The Dietary Supplement Health and Education Act of 1994 ("DSHEA") defines and regulates dietary supplements, including by setting standards for labels on dietary supplements. Dr. Lindsley offers an opinion that "the products marketed by [Defendants] . . . meet the DSHEA guidelines." (*Id.* at 8.) In reaching this conclusion, Dr. Lindsley relied on the federal website relating to DSHEA as well as the relevant Wikipedia page. (Dkt. 238-1 at 73:6–74:6.) He included a bulleted list of various DSHEA requirements that he copied and pasted from Wikipedia. (*Id.* at 74:7–9, 74:21–75:4.)

h) Advertising References

Finally, Dr. Lindsley offers an opinion that Defendants' marketing strategy appears consistent with what is employed for similar products across the industry, including by Hi-Tech. (Dkt. 238-2 at 9–10.) Dr. Lindsley's exert report states:

> Many supplement providers, including Hi-Tech, employ names reminiscent of actual anabolic steroids and the like, so this point, consistently put forth by Dr. Heuer as a marketing offense propagated by the Defense is inappropriate. I reviewed over 20 [unspecified] websites selling similar products, and the marketing strategy for product nomenclature was consistent. Like the Defendant's websites, all had the appropriate disclaimers per [unspecified] FDA, FTC, and DSHEA guidelines.

(*Id.* at 10.)

2. Plaintiff's Daubert Motion

Plaintiff seeks to exclude the report and testimony of Dr. Lindsley, arguing first that his conclusions relating to polypharmacy, dosage, and lack of available data are inadmissible because Dr. Lindsley is not qualified to opine on dietary supplement research and because he failed to use any reliable methodology. Plaintiff also argues that Dr. Lindsley's "concerns" related to Dr. Heuer's patents, potential COPE violations, and Iovate's FTC settlement are inadmissible because they do not involve any scientific or other specialized knowledge and are thus improper subjects

for expert testimony. Finally, Plaintiff argues that Dr. Lindsley is not qualified to testify as to DSHEA compliance or advertising because he has no knowledge or background in these subjects and did not conduct appropriate research or employ any reliable methodology so as to render such testimony admissible.

a) Opinions on Polypharmacy, Dosage and Availability of Scientific Data

An expert is qualified when that expert has sufficient knowledge, skill, experience, training, or education to form a reliable opinion about the issue at hand. *Jones v. Novartis Pharm. Corp.*, 235 F. Supp. 3d 1244, 1251 (N.D. Ala. 2017), *aff'd in part sub nom. Jones v. Novartis Pharm. Co.*, 720 F. App'x 1006 (11th Cir. 2018). The professional experience of an expert must be related to and relevant to the opinion that the expert seeks to offer. *Guinn v. Norfolk S. Ry. Co.*, 441 F. Supp. 3d 1319, 1332 (N.D. Ga. 2020). Thus, an expert cannot testify to matters that "lie outside of his competence." *City of Tuscaloosa*, 158 F.3d at 563. But an expert need not be a specialist in a particular discipline to render expert testimony relating to that discipline. *McDowell v. Brown*, 392 F.3d 1283, 1297 (11th Cir. 2004) ("The proffered physician need not be a specialist

in the particular medical discipline to render expert testimony relating to that discipline.").

Plaintiff argues that Dr. Lindsley is not qualified to testify about the efficacy of dietary supplements because he has no education, training, or expertise in evaluating the efficacy of dietary supplements. (Dkt. 238 at 16–17.) The Court is not persuaded to focus only on expertise in dietary supplements. Dr. Lindsley has knowledge, experience, and education to qualify him as an expert to opine on chemistry and pharmacology as they relate to Defendants' products. Dr. Lindsley's focus throughout his education and training was synthetic organic chemistry, specifically, synthetic methodology, total synthesis, and chemical biology. (Dkt. 238-1 at 7:22–7.) This specialization deals with the effect of chemicals on the human body. (*Id.* at 8:3–7.) Dr. Lindsley then spent seven years in the pharmaceutical industry as a chemist, research fellow, and senior research fellow. (Dkt. 238-2 at 13.) For the past 15 years, Dr. Lindsley has served as a professor of chemistry and pharmacology and as the director and co-director of various initiatives and programs at Vanderbilt University. (*Id.* at 12–13.) All his experience is at the top of the field in chemistry and pharmacology.

Dr. Lindsley's extensive knowledge and experience as a chemist render him qualified to testify regarding chemistry and pharmacology in relation to Defendants' products, regardless of the fact that the majority of Dr. Lindsley's experience is in pharmaceuticals rather than dietary supplements. *See McDowell*, 392 F.3d at 1297; *Jones*, 235 F. Supp. 3d at 1251 (holding expert who had experience in FDA regulations related to medical devices—but not drugs—was nonetheless qualified to testify as an expert on drug-related FDA regulations). Dr. Lindsley ran a large medicinal chemistry group at Merck for seven years, where he studied oncology, or "cancer drugs," and their impact on the central nervous system. (Dkt. 238-1 at 5:13–23, 7:8–14.) As an organic chemist, he studied "the effects of those chemicals on the human body." (*Id.* at 7:22–8:7.) Dr. Lindsley has since led a central nervous system "drug discovery program" at Vanderbilt, where he studies and develops new pharmaceutical therapies for schizophrenia, autism, Parkinson's, and Alzheimer's disease. (*Id.* at 5:14–6:11.) The issue of how molecules, compounds, and chemicals should be investigated, observed, or analyzed is precisely within Dr. Lindsley's area of expertise as a chemist and pharmacologist.

Dr. Lindsley's testimony regarding Dr. Heuer's failure to consider the recommended dosages and the efficacy concerns associated with evaluating individual ingredients without taking into account the novel behavior of proprietary blends is soundly based in Dr. Lindsley's chemistry and pharmacology experience. Dr. Lindsley is qualified as a chemist to testify as a rebuttal expert and point out any flaws in Dr. Heuer's opinion.

The Court also finds Dr. Lindsley's testimony to be reliable. Experience alone is enough for an expert's report, testimony, and opinion to be reliable. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("No one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). The Advisory Committee's Notes to Rule 702 makes this explicitly clear:

> Nothing in this amendment is intended to suggest that experience alone--or experience in conjunction with other knowledge, skill, training or education--may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.

See Fed. R. Evid. 702 Advisory Committee's Note (2000 Amendments); *see also United States v. Brown*, 415 F.3d 1257, 1267 (11th Cir. 2005) (finding an expert's opinions and testimony were admissible where based

on visual comparisons combined with thirty years of knowledge in chemistry that was generally accepted in the field).

The Court finds Dr. Lindsley's qualifications render his polypharmacy, dosage, and lack of scientific data testimony admissible here. Dr. Lindsley's report and testimony are based on the same facts and methodology as Dr. Heuer's opinions, and Rule 26(a) expressly provides that rebuttal experts may be permitted to present evidence that is intended to contradict or rebut evidence on the same subject matter identified by an initial expert witness. Fed. R. Civ. P. 26(a)(2)(D)(ii). Dr. Lindsley's proposed testimony (in this regard) is limited to that of a rebuttal expert—he took the facts as stated by Dr. Heuer and used his extensive knowledge and experience as a chemist to point out where Dr. Heuer was in error in forming his opinions and to poke holes in Dr. Heuer's report and testimony. *See, e.g., Little v. Wash. Metro. Area Transit Auth.*, 249 F. Supp. 3d 394, 414 (D.D.C. 2017) (stating the rebuttal expert "has the experience and qualifications necessary to critique [the opposing expert] and adequately explains the reasons behind her criticisms of [the opposing expert's] report"). Accordingly, Dr.

Lindsley's opinions and testimony regarding pharmacology, dosage and availability of scientific data are admissible.

b) Concerns Regarding Dr. Heuer's Patents, Potential COPE Violations, and Iovate's FTC Settlement, and Defendants' DSHEA Compliance and Advertising

Under Rule 702, expert opinion must, *inter alia*, entail "scientific, technical, or other specialized knowledge" and be "based on sufficient facts or data" as well as "the product of reliable principles and methods." Fed. R. Civ. P. 702. Expert testimony must, therefore, provide "something more than subjective belief or unsupported assumptions." *McDowell*, 392 F.3d at 1298 (citing *Daubert*, 509 U.S. at 590). Plaintiff argues that Dr. Lindsley's "concerns" regarding Dr. Heuer's patents, potential COPE violations, Iovate's FTC settlement, and Defendants' DSHEA compliance and advertising are all examples of improper expert testimony. The Court agrees.

First, there is no evidence that Dr. Lindsley is qualified to opine on whether Dr. Heuer's patents involve supplements that compete with Defendants' products. Nor is there any evidence that Dr. Lindsley has any specialized knowledge as to what constitutes a conflict of interest, aside from his own experience that an expert would be excluded from the

case "if you had any kind of overlapping interest." (Dkt. 238-1 at 39:10–20.) And there is nothing to suggest that Dr. Lindsley's conflict conclusion is reliable or that it would assist the trier of fact, as Dr. Lindsley performed no analysis and applied no specialized knowledge. There is simply no evidence of a conflict.

Dr. Lindsley's conclusions regarding potential COPE violations are similarly deficient. There is no evidence that Dr. Lindsley is an expert in COPE, and he has admittedly had no experience with COPE in the context of dietary supplements or the publications that Dr. Heuer has written. (Dkt. 238-1 at 47:6–14, 47:24–48:10, 48:20–21.) Nor did Dr. Lindsley even know whether Dr. Heuer's publications adopted COPE, indicating that his conclusion lacks reliability. (*Id.* at 101:12–13.) Ultimately, Dr. Lindsley is not qualified to give his COPE conclusion, nor is his conclusion reliable or helpful to the jury. He is just throwing mud.

Dr. Lindsley may not testify as to Iovate's FTC settlement because he has no knowledge or background of the underlying case, the reason for settlement, or even the FTC's regulation of dietary supplements. This is not an appropriate subject for expert testimony. If Defendants wish to ask Dr. Heuer questions about these issues, they may do so on cross

examination. Accordingly, the Court grants Plaintiff's motions to exclude evidence and testimony of Dr. Lindsley regarding Dr. Heuer's patents, potential COPE violations, or the Iovate FTC settlement.

Dr. Lindsley is also not qualified to render a legal opinion that Defendants' product labels meet DSHEA guidelines. His chemistry experience does not qualify him to testify as to whether Defendants are in compliance with the law. The section of his report containing the DSHEA guidelines was copied and pasted directly from Wikipedia. (Dkt. 238-1 at 73:6–74:6.) Dr. Lindsley also stated that he did not know DSHEA's definition of "dietary supplement"; he did not look at the entirety of DSHEA's regulations; he did not look at the entirety of Defendants' advertising; and he ultimately cannot say that their products are DSHEA compliant. (*Id.* at 76:2–8, 82:17–83:4, 86:15–19, 87:14–21.)

Dr. Lindsley is similarly unqualified to testify as to whether Defendants' advertisements are legally compliant or whether their websites contained all the appropriate disclaimers to meet FDA, FTC, and DSHEA guidelines. Dr. Lindsley noted in his deposition that he is not an expert on DSHEA guidelines, FDA regulation of dietary

supplements, or FTC advertising guidelines. (*Id.* at 88:14–24.) There is no indication that Dr. Lindsley is qualified to testify on these matters and thus his testimony regarding DSHEA compliance or other advertising references will be excluded.[2]

C. Defendants' Motion to Exclude Expert Testimony of Linda Gilbert

Under the Lanham Act, 15 U.S.C. § 1114(1), a defendant is liable for trademark infringement if the plaintiff shows (1) its mark has priority and (2) the defendant's mark is likely to cause consumer confusion. *PlayNation Play Sys., Inc. v. Velex Corp.*, 924 F.3d 1159, 1165 (11th Cir. 2019). Plaintiff retained Ms. Linda Gilbert to conduct a survey on two issues that are central to its trademark infringement claims, first, the percentage of potential consumers who consider DIANABOL® a brand name rather than a common or generic name and, second, the percentage of customers who believe Plaintiff's DIANABOL® product and

[2] The Court recognizes that Dr. Heuer could properly be impeached by evidence he has an interest in patents that could benefit from this lawsuit, evidence he published papers in a manner that violated COPE guidelines, or was involved in Iovate's difficulties with the FTC. The Court is not precluding such impeachment. Dr. Lindsey, however, may not offer a professional opinion about these matters as they are beyond the area of his expertise. Indeed, the Court does not believe these subjects require expert testimony.

Defendants' D-Anabol 25 product are affiliated with or made by the same company. (Dkt. 214-2 ¶ 1.) Defendants seek to exclude Ms. Gilbert's testimony, arguing she is not qualified to testify as an expert and her survey was fatally and fundamentally flawed.

1. Ms. Gilbert's Background

Linda Gilbert is the founder of EcoFocus Worldwide, a consumer research firm that specializes in wellness and sustainability. (Dkt. 214-1 at 1.) She holds a Bachelor of Science degree in Agriculture/Food Science from the University of Arizona. (*Id.*) Ms. Gilbert has more than thirty years working in consumer marketing with marketing groups at Fortune 500 companies. (Dkt. 214-3 at 81:11–82:5, 82:19–83:20, 84:4–8, 89:17–22.) She regularly prepares survey questionnaires, sample designs, and analytical plans. (*Id.* at 91:23–93:3.) She has designed over one hundred consumer surveys for clients. (*Id.* at 82:19–25.)

Ms. Gilbert's focus is on health and wellness, including consumer choices and trends regarding wellness and sustainability. (Dkt. 214-1 at 2–5.) She is responsible for launching the EcoFocus Trend Survey, a nationally projectable study of attitudes and actions toward wellness and sustainability that included interviews with more than 11,500 people.

(*Id.* at 2.) She is also responsible for launching the biannual HealthFocus International Trend Survey with respondents from more than thirty countries. (*Id.* at 3.) Her market research has been published in journals and popular media, including *The New York Times*, *The Wall Street Journal*, and *The Chicago Tribune*. (Dkt. 213-3 at 84:9–21.)

2. The Gilbert Report

As explained, the objective of the Gilbert survey was to address two issues—genericness and consumer confusion. (Dkt. 214-2 at 1.) Ms. Gilbert designed and implemented the survey, conducted it online over six days in November 2016, and tabulated and analyzed the data. (*Id.*) Prospective survey participants were asked screener questions to determine whether they qualified for the survey. (*Id.* at 2.) Respondents were required to be 18 years old or older and either have purchased or used nutritional supplements, amino acids, herbal supplements or anabolic steroids for building muscle mass, size, and strength in the past year or planned to purchase or use nutritional supplements, amino acids, herbal supplements or anabolic steroids for building muscle mass, size, and strength in the next two months. (*Id.*) The survey screened out individuals if they or an immediate family member were employed by any

of the following types of businesses: advertising firms, marketing firms, marketing research firms, public relations firms, fitness centers, gyms, vitamin manufacturers, vitamin distributors, vitamin retailers, supplement manufacturers, supplement distributors, supplement retailers, physician offices, and/or nutritionist offices. (*Id.* at 2, App. D, p. 1.) A total of 500 respondents qualified for the survey. (*Id.*)

Respondents were broken into three groups. (*Id.* at 1.) The first group was asked questions designed to determine whether they considered DIANABOL® to be a brand name or a generic name. (*Id.*) These questions followed the widely accepted "Teflon" format for evaluating genericness. Respondents were shown definitions and examples of brand names and common/generic names. (*Id.* at 5, 23–24.) Next, the respondents were asked whether each of six terms were brand name or common/generic name: McDonalds, Hamburger, Ford, Pickup Truck, Starbucks, and Cappuccino. (*Id.* at 6, 24–25.) Respondents who answered at least four of the six qualifying questions correctly moved on to a second set of six more terms to similarly classify: DIANABOL (in all caps); Protein Powder; Muscle Pharm; Creatine; Kre-Alkalyn; and Glucosamine. (*Id.* at 5–6, 26–27.)

The second group was asked questions designed to determine whether they believed D-Anabol 25 and DIANABOL® are made by, affiliated with, or sponsored or approved by the same company. (*Id.*) Survey participants were shown a photo of the DIANABOL® product, and then on the next screen were shown a line-up of five other products, one of which was Defendants' D-Anabol 25, and the others were Trenorol, Muscle Juice, Decacor, and T-250. (*Id.* at 8.) On the following screens, respondents were asked to indicate if any of the five products were made by, affiliated with, or sponsored or approved by the same company as the product shown first. (*Id.*)

The third group served as a control for questions asked to the second group related to likelihood of confusion. (*Id.* at 2.) These participants were shown a similarly shaped control product called Tren 75 in place of D-Anabol-25. (*Id.* at 30.) Images of products and certain survey questions and responses were presented in randomized order. (*Id.* at App. D.)

On the first question related to genericness, the survey results showed that 62% of respondents considered DIANABOL® to be a brand name. (*Id.* at App. A, p.3.) On the second question related to likelihood

of confusion, 48% of respondents believed that D-Anabol 25 and DIANABOL® were made by, affiliated with, or sponsored or approved by the same company. (*Id.* at App. A, p. 9.) Of the control group, 25% of respondents answered that they believed DIANABOL® and the control product to be made by, sponsored by, or affiliated with the same company. (*Id.*) Accordingly, Ms. Gilbert concluded that respondents are 68% more likely to believe that D-Anabol 25 and DIANABOL® product are made by, sponsored by, or affiliated with the same company than they are to say the same about the control and DIANABOL®. (*Id.* at 3.)

3. Defendants' Daubert Motion

Defendants seek to exclude Ms. Gilbert's report and testimony, arguing that she is not qualified to offer trademark-related survey expert testimony and that the survey is fatally flawed and misleading and should thus be excluded. (Dkts. 213; 224.)

a) Ms. Gilbert is Not Qualified as a Trademark Survey Expert

"To fulfill its role as a gatekeeper, the trial court must determine whether the expert has the requisite qualifications to offer the opinions [s]he gives." *Bowers v. Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1349 (M.D. Ga. 2007). The court must accordingly determine whether the expert's

field of expertise is known to reach reliable results for the particular subject matter of her proposed testimony. *Id.* at 1350; *Kumho Tire*, 526 U.S. at 152.

The Court finds Ms. Gilbert unqualified to testify as an expert witness in the subject matter of trademark-related genericness and consumer confusion related surveys. She has no experience or training in this area. She has never designed or executed a trademark-related survey. (Dkt. 213-3 at 11:3–15.) The confusion survey at issue herein was the first and only time she has undertaken a project relating in any way to trademarks or consumer confusion. (*Id.* at 65:16–21.) Ms. Gilbert has never published or otherwise written about consumer confusion, consumer surveys, or any other trademark-related topic, nor has she served as an expert or testified regarding these topics prior to this matter. (*Id.* at 11:24–12:10, 15:22–16:3, 12:14–17, 16:4–9.)

Nor did she review any treatises, journals, or other materials relating to consumer surveys in trademark litigation prior to creating the survey. (*Id.* at 5:1–10.) The only outside materials Ms. Gilbert appears to have consulted to prepare for her expert analysis are the two website printouts she identified in her deposition—websites from two law firms

identified as "Markslaw" and "Nolo.com." (*Id.* at 51:19–52:3, 61:22–64:4.) When asked why she consulted these particular materials, Ms. Gilberts answered, "I just googled and searched on trademark law, and these came up, and they seemed to be very straightforward and informative." (*Id.* at 64:5–11.) She also did not conduct any research regarding the products involved in this case, other competing products, or the dietary supplement industry generally. (*Id.* at 10:5–12:11.)

She does not even claim to be an expert in trademark related genericness or consumer confusion related surveys. She refers to herself as a "futurist," meaning clients rely on her to help consider different paths or trends that might take effect as to certain types of products, such as, "where might we go with calcium supplementation in the future?" (*Id.* at 10:1–20.) She explained that clients hire her "to sort of imagine scenarios that are based on facts and evidence that can help them to sort of see where things might be going in 10 or 15 years down the road." (*Id.* at 10:12–15.) Pepsi, for example, once hired Ms. Gilbert to help determine the "direction" in which soft drinks "might go." (*Id.* at 10:24.) Ms. Gilbert predicted that high fructose corn syrup was "going to get a bad rap and you are going to see soft drink sales decline." (*Id.* at 10:25–

11:2.) She notes in her deposition testimony that "20 years later, we are correct." (*Id.*)

Ms. Gilbert may have ample experience in the field of consumer trends and forecasts, but that experience is insufficient to render her qualified to testify as an expert regarding genericness and likelihood of confusion in a case involving claims of trademark infringement. Indeed, in a separate case involving a separate product, Plaintiff sought to present expert testimony from Ms. Gilbert about another consumer survey she had done. In that case, the Federal Trade Commission sued Plaintiff claiming Plaintiff violated a previous injunction in the way it advertised several weight loss products, including by not having a specific warning on products containing yohimbine. *See Fed. Trade Comm'n v. Nat'l Urological Grp., Inc.*, No. 1:04-CV-3294, 2017 WL 6759868, at *41 (N.D. Ga. Oct. 10, 2017). While Plaintiff admitted it had not included the necessary warning, it sought to admit Ms. Gilbert's expert opinion (based on a consumer survey she had done) that Plaintiff's actual warnings conveyed the same information to consumers as the required warnings. *Id.* at *43. Judge Charles Pannell excluded Gilbert's expert testimony after learning that, in a 2013 deposition in another case,

Ms. Gilbert had admitted she was not "an expert in survey design or analytics." *Id.*; (Dkt. 213-5 at 130:5–8.) Plaintiff argues Ms. Gilbert was being "overly modest" when she stated in her 2013 deposition testimony, "I'm not an expert in survey design or analytics." (Dkt. 214 at 12–13.) Plaintiff says she later clarified that she was "not taking enough credit for what [she] do[es]," explaining that, while she relies on a team in putting together a survey, she designs the methodology, questionnaire, and sampling plan. (*Id.* at 13.) Despite this clarification, Judge Pannell nonetheless found Ms. Gilbert unqualified to testify as an expert in survey design and analytics. Moreover, the issue here goes even beyond whether Ms. Gilbert is qualified to testify regarding survey design or analytics generally. Rather, the relevant inquiry is whether she is qualified to testify regarding trademarks or likelihood of consumer confusion in a trademark infringement case. She frankly admits she has no experience, expertise, or particularized knowledge in this field.

In another Lanham Act case, *Valador, Inc. v. HTC Corp.*, 242 F. Supp. 3d 448 (E.D. Va. 2017), the court excluded the plaintiff's proposed expert where the expert had four decades of experience as a market research consultant but had no prior experience conducting surveys

regarding the likelihood of confusion or proper survey methods in a trademark case. *Id.* at 458. The court also noted that the expert had never testified as an expert in a trademark dispute and had never published on the topic of trademark surveys or likelihood of trademark confusion. *Id.* The facts here closely align with *Valador*. Ms. Gilbert has no training, experience, or specialized knowledge in trademark cases. (*See* Dkts. 213-4; 213-5 at 130:5–8.) She has never testified in a Lanham Act case. (Dkt. 213-3 at 16:4-9.) She did nothing to try to educate herself about the work she was doing apart from reading articles published by two law firms. Just like the expert in that case, Ms. Gilbert is unqualified to offer opinions regarding genericness or the likelihood of confusion in this trademark infringement action.

Other courts have excluded similarly unqualified witnesses from offering expert opinions regarding the likelihood of confusion regarding trademarks. *See, e.g., JFJ Toys, Inc. v. Sears Holdings Corp.,* No. PX-14-3527, 2017 WL 679219, at *4 (D. Md. Feb. 21, 2017) (holding marketing expert's qualifications were "wholly inadequate" to offer testimony about likelihood of confusion where the witness's purported expertise was "devoid of specifics pertinent to the relevant market . . . or the use of the

marks . . . in that same market"); *Radiance Found., Inc. v. NAACP,* 27 F. Supp. 3d 671, 675 (E.D. Va. 2013) (holding witness's "general expertise in the area of surveys and marketing" was insufficient to permit her to testify regarding trademark dilution and likelihood of consumer confusion). The Court applies that same assessment here.

b) The Gilbert Report is Not Reliable

Though the Court finds Ms. Gilbert's lack of qualifications to be an independent basis for the exclusion of her testimony, that fact is further demonstrated by the fundamental flaws in her survey. And a cumulative nature of a survey's defects may also warrant exclusion. *See, e.g., Water Pik, Inc. v. Med-Systems, Inc.*, 726 F.3d 1136, 1145 (10th Cir. 2013) ("several serious methodological flaws" rendered survey "devoid of any probative value and therefore irrelevant" and inadmissible); *1-800 Contacts, Inc. v. Lens.com, Inc.*, 722 F.3d 1229, 1246 (10th Cir. 2013) (sufficiently "serious and pervasive" flaws render survey inadmissible); *Simon Prop. Grp. L.P. v. mySimon, Inc.*, 104 F. Supp. 2d 1033, 1039 (S.D. Ind. 2000) (flaws sufficiently "great" in nature caused "the probative value of the survey [to be] substantially outweighed by the prejudice, waste of time, and confusion at trial"). Ms. Gilbert's survey (1) failed to

evaluate the proper universe of respondents, (2) did not replicate market conditions, and (3) used an improper line-up. As a result, her survey and the expert testimony she seeks to offer based on it are so flawed as to be completely unhelpful to the trier of fact.

(1) Improper Survey Universe

The McCarthy on Trademark treatise makes clear that "[t]he first step in designing a survey" to gauge actual confusion "is to determine the 'universe' to be studied," that is, the segment of the population whose perceptions and state of mind are relevant in this case. 6 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition § 32:159 (5th ed. 2017). This first step is crucial—even asking "proper questions" in a "proper manner" is likely to render irrelevant results if the survey probes the "wrong persons." *Id.*

The appropriate universe of respondents in a trademark-related survey are those consumers "most likely to purchase" the competing products. *Smith v. Wal-Mart Stores, Inc.*, 537 F. Supp. 2d 1302, 1325 (N.D. Ga. 2008) (where allegedly infringing anti-Wal-Mart products were sold exclusively via the Internet, survey universe was overbroad because it was not limited to Internet purchasers with a possible interest in the

anti-Wal-Mart products); *Weight Watchers Int'l, Inc. v. Stouffer Corp.*, 744 F. Supp. 1259 (S.D.N.Y. 1990) (in infringement case involving frozen diet entrees, survey universe was overbroad because it included women who tried to lose weight through exercise only, rather than being limited to women who tried to lose weight through dieting); *Leelanau Wine Cellars, Ltd. v. Black & Red, Inc.*, 502 F.3d 504 (6th Cir. 2007) (where plaintiff's product was sold through mass retail channels and the defendant's product was sold only online and at its winery tasting room, survey was overbroad where it was not limited to wine purchasers who planned to make wine purchases via the Internet or at a winery tasting room).

Here, Ms. Gilbert's survey missed the mark because it was both over- and under-inclusive. *See* 6 McCarthy on Trademarks § 32:161 (collecting cases holding over- and under-inclusive likelihood of confusion surveys unreliable). The survey was over-inclusive because Defendants' D-Anabol 25 product is only sold online though Defendants' website. (Dkts. 57-1 ¶ 4; 164 at 112:12–19.) The survey universe, however, included anyone over 18 years of age who purchased or used within the past year or planned in the next two months to purchase or use

"nutritional supplements, amino acids, herbal supplements or anabolic steroids for building muscle mass, size, and strength." (Dkt. 213-1 at 2.) It was broader than the relevant market. It was also over-inclusive in that 40% of the respondents were women, when the universe of purchasers for the products at issue in this case, which are characterized as "anabolic," are predominately, if not all, male. (Dkt. 213 at 19.)

The survey was also under-inclusive in that it excluded otherwise qualified consumers, arguably some of the most likely consumers to have knowledge of the products at issue. Ms. Gilbert's survey excluded potential purchasers who either worked or had family who worked at fitness centers, gyms, or nutritionist offices. (Dkt. 213-1 at 21.) These broad exclusions prohibited from participation consumers that were most likely to be potential purchasers and most likely to have information about steroids and dietary supplements. Ms. Gilbert's failure to survey a sufficiently close approximation of the correct universe is a

fundamental flaw that contributes to the Court's finding that the survey is not reliable.

(2) Failure to Replicate Market Conditions

Not only did Ms. Gilbert's survey fail to focus on the correct consumer universe, it also failed to replicate market conditions. Although "[n]o survey model is suitable for every case[,] . . . a survey to test likelihood of confusion must attempt to replicate the thought processes of consumers encountering the disputed mark or marks as they would in the marketplace." *Simon*, 104 F. Supp. 2d at 1038 (citing McCarthy on Trademarks § 32:163 (4th ed. 1999) for the principle that "the closer the survey methods mirror the situation in which the ordinary person would encounter the trademark, the greater the evidentiary weight of the survey results"); *Wal-Mart Stores*, 537 F. Supp. 2d at 1327 ("To be valid for the purposes of demonstrating actual confusion in a trademark infringement suit, it is necessary for a survey's protocol to take into account marketplace conditions . . . ."); *Native Am. Arts, Inc. v. Bud K World Wide, Inc.*, No. 7:10-CV-124, 2012 WL 1833877, at *6 (M.D.

Ga. May 18, 2012) (explaining that a "survey must resemble the way consumers would view the products in the marketplace").

Ms. Gilbert used a "sequential line-up" version of a Squirt survey to test likelihood of consumer confusion. In this survey, "respondents are shown the plaintiff's trade dress, and then, after a short delay, shown a line-up of other brands, including the accused product. Respondents are asked if any of them are made by the same company as makes the product initially seen." 6 McCarthy on Trademarks § 32:177. This survey method "is an attempt to replicate the marketplace process of advertising exposure to a brand or trade dress, followed by being confronted in the market with both similar and differing brands or trade dresses." *Id.* In general, a Squirt survey is appropriate where the senior mark is not well known, and the marks often appear side by side in the marketplace. *See Parks LLC v. Tyson Foods, Inc.*, 863 F.3d 220, 233 (3d Cir. 2017) ("Holders of weaker marks more frequently employ a Squirt survey . . . ."). The line-up format is most appropriate in situations where two marks will appear in close proximity in the marketplace, i.e., in the same store or even on the same shelf. *See Limited v. Macy's Merch. Grp. Inc.*, No. 15-CV-3645, 2016 WL 4094913, at *9 (S.D.N.Y. Aug. 2, 2016),

aff'd, 695 F. App'x 633 (2d Cir. 2017); *THOIP v. Walt Disney Co.*, 690 F. Supp. 2d 218, 235 (S.D.N.Y. 2010) ("[A] sequential presentation of the two marks at issue (or array [including controls]) is appropriate only if it reflects a significant number of real world situations in which both marks at issue are likely to be evaluated sequentially or side-by-side."). But where the products at issue "are not sold in the same stores or, for the most part, on the same websites, such a format may over-estimate confusion by forcing consumers to consider the marks in close proximity in a way they would not in the marketplace." *Limited,* 2016 WL 4094913, at *9.

Plaintiff's DIANABOL® product is sold at brick-and-mortar mass retailers and at numerous online websites. DSN's D-Anabol 25 is sold only via the Internet through DSN's website. (Dkts. 57-1 ¶ 4; 164 at 112:12–19.) They do not exist in close proximity to one another. Because a potential purchaser could only encounter D-Anabol 25 online, and only on DSN's website, Ms. Gilbert's failure to replicate marketplace conditions further evidences her survey and testimony as unreliable.

(3) Improper Line-up

Ms. Gilbert's methodology is also unreliable in that she failed to use any product names remotely similar to DIANABOL® and D-Anabol 25 in the product line-up. (Dkt. 213 at 14–15.) "When a survey question begs its answer[,] it is not a true indicator of the likelihood of consumer confusion." *Sunbeam Corp. v. Equity Indus. Corp.*, 635 F. Supp. 625, 634 (E.D. Va. 1986), *aff'd,* 811 F.2d 1505 (4th Cir. 1987). If, in the confusion survey's product line-up, the defendant's product "[stands] out like a bearded man in a line-up with four clean-shaven men[,]" the survey is defective.[3] *THOIP v. Walt Disney Co.*, 788 F. Supp. 2d 168, 183–84 (S.D.N.Y. 2011) (survey was defective because of "demand effects" arising from fact that, in the confusion line-up, the plaintiff's and defendant's products were the only ones remotely similar); *Brighton Collectibles, Inc.*

[3] The Court notes that the parties' briefing, and this Court's opinion, on this issue relies primarily on trade *dress* cases. This is because the Squirt product line-up survey is a lesser preferred method for testing likelihood of consumer confusion but is more commonly used in trade dress cases. 6 McCarthy on Trademarks § 32:177. The "standard and widely accepted survey format" for testing likelihood of consumer confusion is the Eveready format, which does not inform survey respondents what the senior mark is, but assumes that they are aware of the mark from their prior experience. *Id.* § 32:174. Ms. Gilbert's failure to employ the widely accepted format is not a fatal flaw but sheds further light on her lack of experience and qualifications relating to trademark surveys.

v. RK Tex. Leather Mfg., 923 F. Supp. 2d 1245, 1257 (S.D. Cal. 2013) (where only one product/mark in a confusion line-up shared obvious features with the plaintiff's product/mark, the survey was not probative of confusion, tested nothing more than a respondent's ability to "pick the most obvious match," and was excluded).

Besides DIANABOL® and D-Anabol 25, Gilbert's survey showed respondents four other products, Trenorol, Muscle Juice, Decacor, and T-250. (Dkt. 214-2 at 8.) Ms. Gilbert admitted in her deposition that she made no effort to find similarly named products for the line-up, that she chose control products based upon similarity of the bottle/container, and that her line-up control products all had names substantially different from DIANABOL® and D-Anabol 25. (Dkt. 214-3 at 43:11–23.) Ms. Gilbert's failure to include similar product names in the product line-up was another fundamental flaw as it made Defendants' product stand out like the bearded man. This is especially true given the undeniable fact that the market for nutritional supplements like Plaintiff's and Defendants' D-Anabol 25 is flooded with other supplements that have strikingly similar names. This includes nutritional supplements known as "Dianabal-DBol" (sold by iBuy Body); "Dianabal" (sold by Crazy Mass,

LLC); "Dianabol" (sold by Muscle Labs, USA); "Dianabolone" (sold by Pharmasterol.com); Dianobol (sold by Zoelabs.com); "D-Bol/Dianabol" (sold by LegalSteroids.com); and "Dianabol" (sold by Roid-Shop.com). (*See* Dkt. 16-1 ¶ 26,Ex. B); *see also Hi-Tech v. DSN,* No. 1:15-cv-03393-MHC (N.D. Ga. 2015) (companion/precursor case to the present matter). Ms. Gilbert, however, performed no market research to see if other companies used similar names for similar products. She knew it was "important in survey research to replicate the real world market conditions," (Dkt. 213-3 at 25:19–22), but took no effort to do that here. She was not even aware of the other products in the market with similarly sounding names. (*Id.* at 23:5–25:10.) She thus created a line-up that ignored market conditions by including only Defendants' product (her target product) with a similarly sounding name. At her deposition, she would not even say whether the existence of other products with strikingly similar names had any relevance to the issue of whether or not consumers would be confused between Plaintiff's and Defendants' products. (*Id.* at 25:12–17.)

These fundamental flaws not only support the Court's conclusion that Ms. Gilbert is wholly unqualified to offer expert testimony in this

case, but also establish that her survey is so fundamentally unreliable that it would be of no help to the jury. Plaintiff has failed to meet its burden of demonstrating that Ms. Gilbert's testimony is admissible under Rule 702. Defendants' motion to exclude her survey and testimony is granted.

IV. Conclusion

The Court **DENIES** Plaintiff's Motion to Exclude the Expert Testimony of Dr. Fontana (Dkt. 236) and **GRANTS IN PART** and **DENIES IN PART** Plaintiff's Motion to Exclude the Expert Testimony of Dr. Lindsley as stated herein (Dkt. 238). The Court **GRANTS** Defendants' Motion to Exclude Expert Testimony of Ms. Gilbert (Dkt. 213).

SO ORDERED this 28th day of May, 2021.

MICHAEL L. BROWN
UNITED STATES DISTRICT JUDGE